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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,108	03/31/2006	Peter Herold	2006-0446A	7425

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EXAMINER	
HABTE, KAHSAY	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,108	HEROLD ET AL.	
	Examiner	Art Unit	
	Kahsay T. Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 11-22 are pending in this application.

Election/Restriction

2. Applicant's election with traverse of a single disclosed species of Example 5: 6-(4-{4-[3-(2-Methoxy-benzyloxy)propoxy]-phenyl}-piperdin-3-yloxymethyl)-4-(3-methoxy-propyl)-3,4-dihydro-2H-benzo[1,4]oxazine which corresponds to R^1 = [1,4]benzoxazine and Q is absent in the reply filed on 10/20/2008 is acknowledged. The traversal is on the ground that "the Written Opinion of the PCT-Searching Authority was based on the claims as originally filed and not on the instantly filed amended set of claims…the Offices must form their views based on the criteria set out in PCT Rule 13, unless the result of alternative national criteria is more favorable to the applicants. As the latter approach is obviously not the case, the Examiner should clearly follow PCT Rule 13." This is not found persuasive because the United Sates Patent and Trademark Office is *not* bound by the lack of unity determination by another International Searching Authority. MPEP 1875 states that whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner when serving as an authorized officer of the International Preliminary Examining Authority. Thus, the Examiner is *not* bound by any previous determination made. In addition, 37 C.F.R. 1.484 indicates that the international preliminary examination is a non-binding opinion. Finally, 37 C.F.R. 1.499 states that, if the Examiner finds that a national stage application lacks unity of invention under 37 C.F.R.

1.475, the Examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Thus, the determination of lack of unity is proper under the PCT treaty.

The requirement is still deemed proper and is therefore made FINAL.

Note that the examiner searched the elected species and found no prior art, thus, the search was expanded around the core structure of the elected species.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. It is required that applicants amend the claims according to the elected species i.e. Applicants have to limit the definition of R^1 and Q.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 07/13/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 11-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-33 of copending Application No. 11/887,227. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap

between claims 11-22 of the instant case and claims 21-33 of copending Application No. 11/887,227. Note that the copending case is still a new case and is undergoing preexam processing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 11-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-20 of copending Application No. 12/076,221. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between claims 11-22 of the instant case and claims 9-20 of copending Application No. 12/076,221.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of hypertension, glaucoma, cardiac infarction, and restenoses, does not reasonably provide enablement for the treatment of

heart failure, kidney failure and the prevention of hypertension, glaucoma, cardiac infarction, restenosis, heart failure and kidney failure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The scope of the claims is not adequately enabled solely based on the activity related to enzyme rennin and the reduction of the formation of angiotensin I activity provided in the specification. Test procedures and assays are provided in the specification at pages 19-20 and it is concluded that the representative compounds inhibit the formation of angiotensin I with IC_{50} ranging from 10^{-6} to about 10^{-10} mol/l, however, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of the diverse disorders embraced the instant claims. The disorders encompassed by the instant claims (i.e. treatment of heart failure and kidney failure and prevention of hypertension, glaucoma, cardiac infarction, restenosis, heart failure and kidney failure) have been proven to be extremely difficult to treat. Note that the kidney and heart failure is caused by many reasons e.g. diabetes, high blood pressure,

accidents, liver disease, etc. Applicants are claiming the treatment of heart failure and kidney failure regardless of their cause, which has no support in the specification. To this day, no one was able to revive a failed kidney or heart. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

In regard to prevention, the only means available to this day is the treatment of patients suffering from hypertension, glaucoma, cardiac infarction or restenosis, but not the prevention of a healthy person from getting affected by diseases such as hypertension, glaucoma, cardiac infarction, restenosis, heart failure or kidney failure in the first place.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 21, the phrase "A method for the preparation of medicament" is not clear. What medicament? Do applicants mean pharmaceutical composition? If so, this claim would duplicate claim 19.

b. Claim 22 is rejected because it is unclear if the claim is drawn to a method of use or a method of preparing pharmaceutical composition. If it is a method of use, then it should be written in method of use language. If claim 22 is drawn to a preparation of a pharmaceutical composition, then it is duplicate of claim 19. It is recommended that applicants delete claims 21-22.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay T. Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kahsay T. Habte/
Primary Examiner, Art Unit 1624

KH
December 4, 2008